



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20HD; Docket No. CDC-2020-0010]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *Shigella Hypothesis Generating Questionnaire (SHGQ)*. The development of a Shigella Hypothesis Generating Questionnaire will support shigellosis cluster and outbreak investigations. CDC will collect state and local health department furnished shigellosis case data.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0010 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Shigella Hypothesis Generating Questionnaire - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Shigella are a family of bacteria that cause the diarrheal disease shigellosis. It is estimated that *Shigella* causes about 500,000 cases of diarrhea in the United States annually. From 2007 through 2017, there have been 1,046 outbreaks of shigellosis in the United States, with most of these outbreaks attributed to person to person spread. Outbreaks of shigellosis have been reported in a range of settings such as community-wide, daycares, schools, restaurants, and retirement homes. Outbreaks of shigellosis have impacted a range of populations such as children, men who have sex with men, people experiencing homelessness, tight knit religious communities, international travelers, and refugees/displaced persons. Finally, outbreaks of shigellosis have been attributed to a range of transmission modes including person-to-person/no common source, sexual person-to-person contact, contaminated food, and contaminated

water. As part of *Shigella* outbreak investigations, it is common for state and local health departments to conduct comprehensive interviews with cases and contacts to identify how individuals became sick with shigellosis, to identify individuals who could have come into contact with an individual sick with shigellosis, and to identify strategies to control the cluster or outbreak. As person-to-person contact is the most common mode of transmission for shigellosis, and shigellosis is highly contagious, it can be challenging to identify how individuals could have become ill. As a result, comprehensive hypothesis generating questionnaires focused on a range of settings, activities, and potential modes of transmission are needed to guide prevention and control activities.

There is currently no national, standardized hypothesis generating interview data collection instrument for use during single or multistate shigellosis cluster or outbreak investigations. More detailed data about shigellosis cases involved in single or multistate clusters or outbreaks are needed to better characterize the epidemiology of clusters and outbreaks and to identify modes or settings of importance by collecting the following information. This information will not only help inform routine cluster and outbreak investigation activities but also guide awareness efforts and appropriate

prevention strategies. To meet these needs the *Shigella* Hypothesis Generating Questionnaire (SHGQ) was developed.

The SHGQ will be administered by state and local public health officials via telephone interviews with cases of shigellosis or their proxy who are part of a shigellosis cluster or outbreak. The SHGQ will collect information on demographics characteristics, household information and family member event and activity attendance, clinical signs and symptoms, medical care and treatment information, travel history, contact with international travelers or other ill individuals, event and activity attendance, limited food and water exposure, work, visit, and volunteer locations, childcare and school attendance, and recent sexual partner(s) and activity.

This interview activity is consistent with the state's existing authority to investigate reports of notifiable diseases for routine surveillance purposes; therefore, formal consent to participate in the activity is not required. However, cases may choose not to participate and may choose not to answer any question they do not wish to answer. It will take health department personnel approximately 45 minutes to administer the questionnaire to an estimated 1500 patient respondents. This results in an estimated annual burden to the public of 1,125 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Shigellosis case patients identified as part of outbreak or cluster investigations	Shigella Hypothesis Generating Questionnaire	1500	1	45/60	1,125
Total					1,125

Jeffrey M. Zirger,

Lead,

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Office of Scientific Integrity,

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[FR Doc. 2020-03650 Filed: 2/24/2020 8:45 am; Publication Date: 2/25/2020]